DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-70

June 21, 1999

Gustavo Barni, Owner/President
Atlas Operations, Inc.
1910 N.W. 18th Street
Suite #1
Pompano Beach, Florida 33312

Dear Mr. Barni:

This letter concerns your product "Longevity". The product label declares as an ingredient 2(3H)-Furanone Di-hydro, also known as gamma-butyrolactone (GBL).

Representatives of the Food and Drug Administration (FDA), Florida District Office, inspected your company on April 22, 1999, to determine the status of your operations with respect to manufacturing and distributing products containing GBL. The investigators also expressed FDA's concern about the safety and legality of your product and attempted to determine your company's intentions with respect to the continued marketing of the product. On that date, Melani Barni advised our Florida District Investigators that your firm had ceased distribution of the product several months ago because of safety concerns and that it would be difficult to recover product shipped four to six months ago.

FDA has serious public health concerns about products such as yours that contain GBL as an ingredient. Because of these concerns, FDA has made available a "Talk Paper" to alert the public. FDA is prepared to pursue appropriate legal sanctions under the Federal Food, Drug, and Cosmetic Act (the Act), including seizure and injunction, as necessary to protect the public health.

GBL is a potent pharmacological agent that is closely related to, and rapidly metabolizes into, the drug substance gamma-hydroxybutyrate (GHB). GHB is a drug substance that is legally available in the United States only as an investigational new drug for specified uses. There is considerable information available concerning the known physiological effects and toxicity of GHB. Its primary pharmacological effect is that of a central nervous system depressant. Toxicity is characterized by coma, depressed respiratory rate, low body temperature, slow heart rate, and vomiting.

FDA has received at least 55 reports of adverse effects associated with the use of a number of different products that contain GBL. Many of these reports indicate significant effects on mental status. In 19 cases, the consumers were reported unconscious or comatose, and a number of these persons required intubation for assisted breathing. Other reported adverse events include seizures, vomiting, muscle spasms, respiratory depression (decreased breathing rate), and bradycardia (slow heart rate). One death of a GBL consumer was reported as being related to "idiopathic cardiac arrhythmia" and drug-induced sleep. The mean age of individuals reporting an adverse event was 29 years (range 11-71 years), with at least five reported adverse events occurring in individuals under 18 years of age. The adverse events thus far reported for GBL-containing products are consistent with the known toxicity of GHB as reported in scientific literature.

GBL, like GHB, is a powerful hypnotic substance known to produce significant and potentially dangerous sedating effects. Therefore, FDA considers GBL-containing products, such as "Longevity", to be drugs as described in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act). Such products are also new drugs, as defined in section 201(p) of the Act, which require FDA approval under section 505(a) of the Act prior to marketing. The marketing of new drugs without an approved new drug application is prohibited under section 301(d) of the Act.

"Longevity" is also misbranded under section 502(f)(1) because the labeling fails to bear adequate directions for use and is false and misleading as it suggests that the products are safe and effective for their intended uses when this has not been established [section 502(a)]. The introduction or delivery for introduction into interstate commerce of misbranded drugs is prohibited under section 301(a) of the Act. The misbranding of a drug while held for sale after shipment in interstate commerce is prohibited under section 301(k) of the Act.

The agency recognizes that "Longevity" is represented as a dietary supplement. The product does not meet the definition of a dietary supplement under section 201(ff) of the Act, however, because it is not marketed and used to augment or otherwise supplement the diet. GBL-containing products like "Longevity" are being marketed and used to achieve the powerful pharmacologic, hypnotic, and sedative effects associated with GHB. Such products are not dietary supplements as described in section 201(ff)(1) of the Act.

Even if "Longevity" met the definition of a dietary supplement, it is also a drug, and can be regulated as such. Moreover, even as a dietary supplement, it would violate other provisions of the Act. For example, the data collected thus far by the Agency show that "Longevity" presents a significant and unreasonable risk to consumers under section 402(f)(1)(A) of the Act.

We note that you have apparently ceased manufacturing and distributing "Longevity". Please be aware that resumption of the manufacture and distribution of the product could result in enforcement action by FDA without further notice. The Act provides for seizure or injunction against manufacturers and distributors of violative products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to your intentions regarding manufacture and distribution of this and any other GBL-containing products.

Your reply should be sent to the attention of Timothy J. Couzins, Compliance Officer, Florida District, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4728.

Sincerely,

Douglas D. Tolen
Director, Florida District